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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,312	10/25/2005	Stephen Berezenko	063572-5001US	7926

24341 7590 04/15/2009
MORGAN, LEWIS & BOCKIUS, LLP. (PA)
2 PALO ALTO SQUARE
3000 EL CAMINO REAL
PALO ALTO, CA 94306

EXAMINER

HOBBS, LISA JOE

ART UNIT	PAPER NUMBER
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1657

MAIL DATE	DELIVERY MODE
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04/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,312	Applicant(s) BEREZENKO ET AL.	
	Examiner Lisa J. Hobbs	Art Unit 1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-14 and 16-21 is/are pending in the application.
- 4a) Of the above claim(s) 11, 12, 16-18 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-10, 13, 19, 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election without traverse of Group I in the reply filed on 25 August 2008 is acknowledged. Apparently, the previous examiner was limiting the examination of claim 13 to the subject matter previously elected in the instant application, a pharmaceutical composition comprising an isolated mutant human or mammalian serum albumin, while indicating that the additional subject matter, the nucleic acid sequence or the expression cassette, would not be examined with this group. However, in light of applicant's amendments to the claim this discussion is moot as the claim is now limited to the subject matter elected in Group I.

Drawings

The amendments to Figs. 15, 16, and 20 are acknowledged and accepted.

Claim Status

Claims 1-3, 6-14 and 16-21 are pending in the instant application. Claims 4, 5, and 15 have been cancelled by amendment; claims 11, 12, 14, 16-18, and 21 have been withdrawn from further consideration pursuant to 37 CFR 1.12(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim. Claims 1-3, 6-10, 13, 19, and 20 are under examination in this Office Action.

Objection to Specification

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The corrections to the specification made by amendment with the response of 25 August 2008 are acknowledged.

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code, see pages 5 and 17, for example. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

The disclosure is objected to because it lacks a section entitled “Brief Description of the Drawings”. Applicants have described the drawings, including added Figs. 20a and 20b which were converted from Table 1, but have not placed them in a separate section as required. The title “Detailed Description of the Invention” should be moved to the end of the figure descriptions, at page number 16 (as defined by the amendment of 25 August 2008) above/replacing the title “Materials and Methods”.

Objection to Claims

Those objections which are not reiterated are withdrawn in light of applicant’s amendments with the response of 25 August 2008.

Claim 2 is objected to because of the following informalities: the phrase “physiological characteristics causes a change in cell adhesion to a substrate, percentage viability of cell, or cell growth of cells in culture” should be re-written to indicate that the physiological characteristics

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are caused by the change in the polypeptide claimed, or that the changes are caused in the cells because the peptide is administered to the cells. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Those rejections previously made under 35 USC 112, second paragraph, which are not reiterated are withdrawn in light of applicant's amendments with the response of 25 August 2008.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, and 19, with dependent claims 6-9 and 13, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. As amended, claims 1-3 have number agreement inconsistencies regarding the amount of physiological characteristics that are altered subsequent to the recited mutations. Claims 1 and 3 recite "an altered physiological characteristics", while claim 19 recites "an altered physiological characteristic...". Claim 2 recites "altered physiological characteristics causes a change in...". It is unclear how many physiological characteristics are intended to be claimed as resulting from the mutations recited.

Claims 1, 8, 9, and 10, with dependent claims 2, 6-7, 13, 19-20, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite

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mutations at points X_1 , X_2 , etc., but do not specify a relationship between actual positions in the SEQ ID NOs and the XX mutations. The position designation X_1 or X_2 or X_x could be different depending on how the sequence is read, since there are ten SEQ ID NOs and multiple X_x s. Only SEQ ID NO: 1 identifies Xaas throughout, and even in this SEQ ID NO it is unclear how the X_x designation relates to specific SEQ ID NO positions. Apparently, using the identifiers from the claim as previously written, X_1 appears to be at position 67 in SEQ ID NO: 1, while the first Xaa in SEQ ID NO: 1 is at position 30, thus X_1 is not the first Xaa recited in the SEQ ID NO.

MPEP 2422.03 states that “37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the “Sequence Listing” by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as “residues 14 to 243 of SEQ ID NO: 23” is permissible and the fragment need not be separately presented in the “Sequence Listing.” Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules”.

Applicant is required to present the claims in such a way that the specific desired mutations are noted in the proper format for sequence designation. For example (only): “SEQ ID NO: 253, position 594 is any one of A, F, G, C, D, E” while the SEQ ID NO notes what the original wild-type sequence is. The wild-type sequences of the human and mammalian albumins

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of the instant invention are essential information, since the current claims recite mutations of them, and may not be merely referred to as being present in a particular database, which database may be updated and the sequence changed to be different than that used to create the instant mutations.

Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 is indefinite because a mutant of human serum albumin is claimed with a mutation of Asn99His, Asn99Asp, or His67Ala, however there is no SEQ ID NO assigned to such a mutant and one skilled in the art would not know where a desired position for such mutation is present and where the sequence ends or starts, for example. Thus, a SEQ ID NO should be assigned to such a mutant.

The rejection of this claim is maintained. Although applicants have amended claim 10 to recite that the mutant of interest is a mutant of SEQ ID NO: 1, the particular sites where mutations are envisioned are still not properly identified. First, the position X_1 or X_2 could be different depending on how the sequence is read, since SEQ ID NO: 1 merely identifies Xaa's throughout. Apparently, using the identifiers from the claim as previously written, X_1 appears to be at position 67, while the first Xaa in SEQ ID NO: 1 is at position 30 and thus X_1 is not the first Xaa recited in the SEQ ID NO. MPEP 2422.03 states that "37 CFR 1.821(d) requires the use of the assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences regardless of whether a given sequence is also embedded in the

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text of the description or claims of an application. This requirement is also intended to permit references, in both the description and claims, to sequences set forth in the "Sequence Listing" by the use of assigned sequence identifiers without repeating the sequence in the text of the description or claims. Sequence identifiers can also be used to discuss and/or claim parts or fragments of a properly presented sequence. For example, language such as "residues 14 to 243 of SEQ ID NO: 23" is permissible and the fragment need not be separately presented in the "Sequence Listing." Where a sequence is embedded in the text of an application, it must be presented in a manner that complies with the requirements of the sequence rules".

Second, there are multiple Xaas identified in SEQ ID NO: 1, two of the Xaas have been defined in the claim, and been defined as other than the possibilities recited in SEQ ID NO: 1, but no guidance is provided on the other Xaas of SEQ ID NO: 1. These Xaas could be varying as recited in the misc_features of SEQ ID NO: 1 or not, as with the two Xaas disclosed. The disposition of the other Xaas can be defined by disclosing which Xaa positions are defined as X₁ and X₂.

Claims 1-3, 8-10, 19-20, with dependent claims 6-7 and 13, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims appear to be reciting specific groups possessing the desired traits, such as "altered physiological characteristics", a list of three characteristics, a list of mutations at certain positions, etc., but none of the claims lists the desired mutations or physical characteristics in proper Markush format. Without proper wording of the lists, it is unclear if the groups are exclusive or

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encompassing of other elements, thus the proper metes and bounds of the claim cannot be determined.

Claim 1, in a rejection maintained from the previous action as applied to claim 4, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant states at several places in the specification that the wild-type human and mammalian albumin sequences are present in various databases. SEQ ID NOs: 2-10, human and other mammalian albumin sequences, are also disclosed; SEQ ID NO: 1 discloses a human albumin sequence with variables present at 11 places in the sequence. While SEQ ID NO: 1 does disclose a version of the human albumin sequence, there are eleven amino acids which are not provided with original amino acid information, so that embodiments of the claim which are close to 100% may be clearly understood. The metes and bounds of this claim are unclear; if the mutant has non-wild-type mutations at all eleven positions, it is not clear how claim 9 can specify that at least one mutation at one of four positions is encompassed. Applicant argues that the specification clearly discloses the sequence of human serum albumin and that SEQ ID NO: 2 is the sequence with a particular GenBank accession number. Accession numbers may not be used to delineate sequences, and specific SEQ ID NOs are required, because those of skill in the art are constantly updating and changing GenBank entries with information as it is developed from ever more specific assays and methods. GenBank does not freeze a SEQ ID NO as of the date of filing, therefore an accession number may not be used to define the metes and bounds of a sequence claim. If SEQ ID NO: 2 is the wild-type sequence that is intended as the base sequence

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for this series of mutations, and not all eleven mutations are required in all embodiments of the claims, then the claims should recite SEQ ID NO: 2 with the mutations defined as positions within SEQ ID NO: 2 and the notation that the instant mutation encompasses one or more of the recited sites being other than [whatever amino acid it naturally is].

Claims 3 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 recites that the mutant of interest comprises “**one** of the sequences” of SEQ ID NOs: 2-10 wherein “**at least one**” of the stated residues of that sequence is mutated. However, as amended, claim 8 recites that the mutant is according claim 3, but comprises a sequence that has 11 mutations (X₁ through X₁₁), “wherein X₁ is any one of**and** X₁₁ is any one of...”(emphasis added). It is unclear how many mutations the mammalian sequences are intended to have; the metes and bounds of these claims are unclear.

Claim 19 recites the limitation "altered metal binding affinity and an altered physiological characteristic" in line 2. There is insufficient antecedent basis for this limitation in the claim. Independent claim 1, from which claim 19 depends, does not recite that the change in physiological characteristics is in addition to the change in metal binding affinity, it recites that the mutant has an “altered metal binding affinity or an altered physiological characteristics [sic]”.

Claim 20 recites the limitation "said one or more physiological characteristics" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. As amended,

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independent claim 1, from which claim 20 depends, does not recite “one or more physiological characteristics”.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and eXact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 6-9, 13, 19, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant invention is directed to any isolated mutant human serum albumin having at least 90% sequence identity to native human serum albumin or any isolated mutant mammalian serum albumin having at least 90% sequence identity to its concomitant native mammalian serum albumin and comprising any combination of one or more of the various mutations described for SEQ ID NOs: 1-10.

The instant specification does not describe all possible mutant mammalian serum albumins that are 90% or more identical to native HSA, or other MSA, and which comprise any combination of one or more of the mutations for SEQ ID NOs: 1-10 recited in claims 1, 3, 8 and 9. Therefore, the aforementioned claims lack adequate written description.

Accordingly, in the absence of sufficient recitation of identifying characteristics, the specification does not provide adequate written description of the claimed genus of such group of proteins, i.e. mutated mammalian serum albumins comprising any combination of the mutations recited for SEQ ID NOs: 1-10 in claims 1, 3, 8 and 9.

Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir.1991), states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in *possession of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116). The skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993).

In the instant case it is uncertain what portions of SEQ ID NOs: 1-10 should be a part of the mutated human or mammalian serum albumin as claimed and still retain a function of altered binding activity or other natural function of the native peptide. The specification does not disclose all mutants with the recited substantial identity to the SEQ ID NOs: 1-10, comprising mutations at any combination of the residues recited, and the specific functions of the claimed genus of mutants is unknown; Applicant is not in possession of all possible mutations in the human or mammalian serum albumin, for example. Above all, there is no correlation between

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the structure and function of the mutated human or mammalian albumin that comprises all the recited variations of SEQ ID NOs: 1-10 because any mutant of human or mammalian serum albumin does not necessarily possess a metal binding affinity or the characteristics of the native serum albumin. Thus, because of the multiplicity of potential mutants there is no correlation between structure and function.

Therefore, for all these reasons the specification lacks adequate written description, and one of skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention i.e. all possible mutated human or mammalian serum albumins, which also comprise any combination of mutations listed for SEQ ID NOs: 1-10, at the time the instant application was filed.

Response to Arguments

Applicant's arguments filed 25 August 2008 have been fully considered but they are not persuasive. Applicants argue that "the specification provides ample description of representative species by actual reduction to practice. For example, page 6 and 7 discloses the numerous mutants where a residue at one of the positions ... is changed, and the actual reduction to practice of numerous mutants such as His67Ala, Asn99Asp, and Asn99His". However, page 6 discloses that "the following mutations are postulated to result in decreased metal binding affinity" and "mutation of a side-chain...that is "likely to give rise to...modulated metal affinity" and page 7 discloses that the "H bond is expected to stabilize the "switched" form" and "it is predicted that the following mutations...might influence...metal/fatty acid binding" and "mutations...can also have similar impact on cell adhesion and/or growth".

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Applicants argue that pages 6 and 7 recite structure function correlation and functional changes caused by the structural changes. However, as disclosed in the specification, there is no specific teaching of which mutants actually function in the claimed manner besides those specifically named above.

Claims 1-3, 6-9, 13, 19, and 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a mutant human serum albumin that comprises SEQ ID NO: 1 with the disclosed mutations N99A, N99H, and H67A, and all other amino acid residues remaining wild-type, does not reasonably provide enablement for any mutant human serum albumin that comprises 90% identity to SEQ ID NOs: 1-10 with any combination of the mutations recited in claims 1, 3, 8 and 9. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention.

The enablement requirement refers to the requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of Experimentation Necessary; Amount of direction or guidance presented; Presence or absence of working examples; Nature of the Invention; State of the prior art and Relative skill of those in the art; Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988)). The factors most relevant to the instant invention are discussed below.

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The amount of experimentation required to practice the claimed invention is undue as the claims encompass unspecified proteins, i.e. mutant human or mammalian serum albumins that have 90% identity to SEQ ID NOs: 1-10 and which comprise any combination of the mutations recited in claims 1, 3, 8 or 9. As claimed, the mutant mammalian serum albumins can have up to 10% changes in the native serum albumin protein and also must comprise any one or more of the mutated residues outlined in the claims. Further, there is no binding specificity that can be assigned to mutants where the structure of the mutant is unknown. Here, the instant specification does not demonstrate or provide any guidance what would be the structure of a mammalian serum albumin that comprises 90% identity to SEQ ID NOs: 1-10 and also comprises any or all of the mutated residues disclosed in the claims, or whether a derivative of such a mutant would exhibit the same characteristics as the native protein. Thus, the experimentation is undue because one skilled in the art must find infinite relevant fragments of SEQ ID NOs: 1-10 that have the disclosed functions.

In addition, there is no experimentation that would refer to a disclosure in regards to determination of how one would determine the part of SEQ ID NOs: 1-10 that should be included in mutated mammalian serum albumin and also comprise the mutations claimed. Thus, due to the large quantity of experimentation necessary one skilled in the art would not know how to make and use the invention commensurate in scope with the claims.

There is no predictability in regards to which potential changes in the mutant mammalian or human serum albumins comprise 90% sequence identity to SEQ ID NOs: 1-10, also comprise the mutated residues claimed, and would be conserved and retain the native function of the

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human or mammalian serum albumin or a desired metal binding activity. In this case, the necessary guidance is not provided.

Further, the prior art is unpredictable in regards to any mutant serum albumin that possesses 90% identity to SEQ ID NOs: 1-10 and which comprise any one or more of the mutations described, for example.

The state of the prior art provides evidence for the high degree of unpredictability of mutated proteins because of the variability of the protein's structure that can affect its function, for example. Seffernick et al. (J. Bacteriology, vol. 183, pages 2405-2410, 2001) teach that polypeptides that are identical along relatively long stretches of their respective sequences exhibit different function. In the instant application, the rejected claims are drawn to any mammalian serum albumin comprising from 0% to 10% variation and comprising one or more of the mutations recited, thus the claims would encompass a genus of proteins including their fragments and variants that do not necessarily have the same function.

The specification lacks adequate guidance/direction to enable a skilled artisan to practice the claimed invention commensurate in scope with the claims in regards to any mutated human or mammalian serum albumin that comprises 90% identity to SEQ ID NOs: 1-10 and any one or more of the mutations recited in the claims.

The working examples provided do not rectify the missing information in the instant specification pertaining to the claimed unknown kind or number of mutated mammalian or human serum albumins as recited because one skilled in the art would have to engage in undue experimentation to compose various mutants that comprise different variants of SEQ ID NOs: 1-10 as well as one or more of the mutations recited in claims 1, 3, 8 or 9 and see whether the 90%

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identical fragments to SEQ ID NOs: 1-10 have desired function claimed. Thus, one skilled in the art would have to engage in extensive undue experimentation in choosing specially the derived proteins and then examine them for their function.

Therefore, it is clear that the specification does not provide support for the broad scope of the claims that encompass an unspecified number of mutated human or mammalian serum albumins that are 90% identical to SEQ ID NOs: 1-10 and which comprise one or more of the variations recited in claims 1, 3, 8 or 9.

Also, absent direction or guidance regarding any mutated human serum albumins that comprise SEQ ID NO: 1, one skilled in the art would not be able to practice the claimed invention commensurate in scope with the claims.

Thus, for the aforementioned reasons, the specification is not considered enabling for one skilled in the art to make and use the claimed invention as the amount of experimentation required is undue, due to the broad scope of the claims regarding any mutated human serum albumins that comprise at least 90% sequence identity to SEQ ID NO: 1, the lack of guidance and working examples provided in the specification, and the high degree of unpredictability. Thus, practicing the method would constitute undue experimentation.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 3, 6-8, 13 and 19 under 35 U.S.C. 102(b) as being anticipated by Sargent et al., ((1986) Accession No. P02770) as evidenced by Andersson et al. ((1991) Immobilized metal ion affinity chromatography of serum albumins, Bioseparation 2: 15-22) is withdrawn in light of the amendments to the claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa J. Hobbs whose telephone number is 571-272-3373. The examiner can normally be reached on Monday to Friday, 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lisa J. Hobbs/
Primary Examiner
Art Unit 1657

ljh